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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/303,315      | 04/30/1999  | EUGENE S. PEARLMAN   | 108604/002          | 8170             |

7590 02/05/2003

RASHIDA A. KARMALI, ESQ.  
99 Wall Street  
New York, NY 10005

EXAMINER

CLOW, LORI A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1631

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DATE MAILED: 02/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/303,315

Applicant(s)

PEARLMAN, EUGENE S.

Examiner

Lori A. Clow, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 21-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Applicants' arguments, filed 27 November 2002, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-4 and 21-24 are currently pending.

#### ***Claim Rejections - 35 USC § 112***

Claim 22 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 is unclear as to its significance. How does the limitation that the m clinical tests have an equal number of bits (data) limit the apparatus claimed? Applicant claims that claim 22 has been cancelled and then states that there has been an amendment to claim 22, however, there is no amendment to claim 22 in Paper No. 20, submitted 27 November 2002. This is confusing and it is not clear if claim 22 is cancelled or still pending.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-4 and 21-24 remain rejected under 35 U.S.C. 102(e) as being anticipated by Armstrong et al. (US 6,099,469). As stated previously, Armstrong et al. meet the limitations of the steps set forth in the generic claims and the apparatus of Armstrong et al. meets all of the limitations of the generic apparatus of the instant invention.

As set forth, Armstrong et al. disclose a disease specific algorithm for use in a computer-assisted method that analyzes what clinical tests should be performed. The particular disease state of Armstrong et al. is acute myocardial infarction. A first test is performed on the sample, then, based upon result comparisons with preset guidelines, a second test is run. In the conditions set forth in column 3, line 52-column 4, line 12, it is clear that the invention of Armstrong provides means for omitting the execution of unnecessary assays while ensuring that all necessary combinations of laboratory tests are covered. Furthermore, the reflex algorithm of the invention automatically selects appropriate markers for a given clinical situation such that human decision-making is eliminated. The rejection is maintained.

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Claims 1-4 and 21-24 remain rejected under 35 U.S.C. 102(e) as being anticipated by Carlson et al. (US 6,140,065).

As set forth previously, Carlson et al. (US 6,140,065) disclose computer-assisted methods for diagnosing a disease state based upon a reflex algorithm. Applicant argues that the amendments to the claims make them allowable over Carlson. However, as stated above in reference to Armstrong et al., the claims state that test are run on a sub-group showing abnormality, thereby not allowing UNNECESSARY clinical tests to be carried out in duplicate or to be ordered by an outside operator. However, this does not imply that the tests still cannot be run or that an operator is not utilized when a NECESSARY test is indicated. The rejection is maintained.

Claims 1-4 and 21-24 remain rejected under 35 U.S.C. 102(b) as being anticipated by Adlassnig et al. (Artificial Intelligence in Medicine, (1995) Vol.7, pages 1-24).

Adlassnig et al. disclose the HEPAEXPERT-1 computer algorithm that is useful in obtaining a diagnosis of HBV infection. As shown in figures 2 and 3 typical serology for a variety of types of HBV infection are used for identifying which clinical tests to run. Rules are written in to computer memory for normal and typical scenarios of HBV infection and the computer goes through a variety of test combinations to establish a diagnosis. The programmed computers of Adlassnig et al. meet all of the limitations of the instant claims.

All claims are rejected.

**THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### *Inquiries*

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (703) 306-5439. The examiner can normally be reached on Monday-Friday from 10am to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

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January 28, 2003

Lori A. Clow, Ph.D.

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*Lori A. Clow*

*Marianne P. Allen*

MARIANNE P. ALLEN  
PRIMARY EXAMINER  
GROUP 1800  
*AU 1631*